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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,956	07/09/2001	John N. Feder	8907-091-999	8853

7590 12/03/2003

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EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,956	FEDER ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,17,18,20 and 21* is/are rejected.

7)☐ Claim(s) *16 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 14-15, 17-18 , and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 14-15, 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO.1, does not reasonably provide enablement for any peptide under formula 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Note, in light of Applicants response, the rejection has been changed to a scope of enablement rather than an enablement.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above

factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Applicants argue that a single working example "in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled." Thus, Applicants state that the claims 16 and 19 should not be included in the rejection since claims recited specific substitutions for the amino acid formula. In light of these remarks, the rejection has been amended to exclude these claims and to change from a straight enablement to a scope of enablement rejection. Since the issues are the same in both rejection, the basis for the rejection is as recited in the previous office action and Applicants arguments raised in traversing the rejection have been addressed.

In traversing the remaining rejected claims, Applicants argue that the claims are not too broad in light of the skill in the art. Applicants state that the specification provide SEQ ID NO. 1 and that "it is rather straightforward for one of skill in the art to make conservative substitutions in SEQ ID NO:1" and to test such a peptide for activity on TfR, as guided by the specifcation on page 26. Applicants state that the concerns raised by Ngo et al. are not pertinent to the claims in issue since "it is straightforward for one of skill in the art to construct a compoind having the residue meeting the characteristics identified for each X position in formula (I), using, for example, Table I on page 13 of the specification as a guide, and the test its activity on the function of TfR." Applicants emphasize that since the claimed invention only requires conservative substitutions at one or more of sixteen positions out of seventeen, that undue experimentation is not necessary. Only experimentation necessary is activity of a cell based assay described in the specification, no unlike the routine screening of hypbridomas allowed in *In re Wands*.

Applicant's arguments filed 8-26-03 have been fully considered but they are not persuasive.

Firstly, Applicants emphasize that the claims utilize conservative substitutions. However, this is not entirely the case in all of the substitutions. For example, X3 can be an acidic or an aliphatic residue. In the specification on page 10-11, Aliphatic amino acids "refers to a a hydrophobic amino acid. . ." and acidic amino acid "refers to a hydrophilic amino acid." A hydrophobic amino acid are not a conservative substitution for a hydrophilic amino acid since they have complete opposite characteristics. Further, the substitutions in positions X2 state a hydrophobic residue. The specification exemplify amino acids such as "pro, phe, trp, met, ala, gly, tyr, ile, leu, and val" as a possible substititutions. However, it is well known in the art that tyrosine does not form a conservative substitution with val, ile, leu, met, ala. Thus, Applicants assertion of conservative substitutions is not entirely correct.

Even if the claims were limited to strictly recognized conservatives substations, the claims would fail the enablement requirement. As stated in the previous office action, Ngo et al. and Rudinger et al. both illustrate the effects a single substitution can have on the ability of a peptide or protein to bind to its recognition site. Indeed it is well known that a single substitution can have deleterious effects on the activity of the protein. The reference cited does not make a distinction between conservative and non-conservative amino acids. It is not as simple making as peptide according to formula I and determining activity based on an assay. Rather, one would be burdened with determining what modification to make and conducting assay methodology to see if the modified peptide retained the desired activity. As stated in the previous office action, although computers can be used to design drugs, "for the most part technicians must still screen many, many compounds to find their magic bullets." (see Science page 441). The article concludes that computer models are not an effective method of determining drug activity. "Even modest gains in the ability to predict drug activity from structural data will be enough to delight some computational biologist.

'Developing drugs is a vague science in which you synthesize a large number of compound." The specification does not provide any guidance in making these determinations. Once potential candidates have been found in this vague science, one of ordinary skill in the art would have to determine the pharmacokinetics, such as drug absorption and drug clearance, of the analog before it could be utilized in the treatment of iron overload disease. This is because the one could not predict, based on structural alone that the peptide would be effective in threat said disorders. Thus undue experimentation is required to practice the claimed invention.

For these reasons the rejection is maintained.

2. Claims 16 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta
12/1/05